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09/909,733	07/20/2001	Leo Martis	DI-4389 DIV	2820

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,733	Applicant(s) Martis
	Examiner David Lukton	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 3, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-8, 32, and 33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *32 and 33* is/are allowed.

6) ☒ Claim(s) *2-5, 7, and 8* is/are rejected.

7) ☒ Claim(s) *6* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Pursuant to the directives of paper No. 11 (filed 12/3/02), claim 8 has been amended, claims 32-33 added, and claims 19-31 cancelled. Claims 2-8, 32, 33 remain pending. Applicants' arguments filed 12/3/02 have been considered and found persuasive in part. The rejection of claim 6 under 35 USC §103 is withdrawn. Claim 6 is objected to because of its dependence on a rejected claim. In addition, claims 32-33 are characterized as allowable.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 2-5, 7, 8 are rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609).

As indicated previously, Okamoto discloses (e.g., col 12, lines 66-67) a peritoneal dialysis solution in which the glucose is present to the extent of 0.005 - 78 g/liter, and the pH is 5.5-6.5; Klein teaches (e.g., col 4, line 21+) compositions comprising peptides for peritoneal dialysis. In addition, Klein teaches (col 12, line 40+) that the peptides can be "combined with any osmotically balanced aqueous solution [that is] appropriate...".

Applicants have begun by pointing to *In re Cruciferous Sprout Litigation*. A USPQ citation has not been provided, but the assumption at this point is that the document identified as "Lexis 17185" is the same as **64** USPQ2d 1202. In the opinion of "*Cruciferous Sprout*", reference is made to *Pitney Bowes Inc v Hewlett Packard Co* (**51** USPQ 2d 1161). At issue in these cases was the question of how much significance should be given to the preamble. The patents in litigation were 5,725,895, arising from application 08/528858, as well as one patent resulting from a continuation of application 08/528858, and a divisional of application 08/528858. Claim 1 of USP 5,725,895 is the following:

> 1. A method of preparing a food product rich in glucosinolates, comprising germinating cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.

However, the situation represented by this claim is not the same as that in the instant case.

The "food product" in USP '895 was not a fully defined mixture of organic and inorganic compounds. Only some of the compounds present have been identified, and the exact composition cannot be controlled. This contrasts starkly with the present situation, where fully 100% of all compounds present are known, and the exact amounts present are known as well. The chemist who has prepared the mixture of the instant claims has total control over the composition. As such, it is the ingredients themselves that largely define the composition. Moreover, if applicants argument regarding the preamble were correct, the following claim 100 would be patentable over claim 1 of USP '895, and following claim 101 would be patentable over claim 1 of USP '895, as well as being patentable over claim 100:

> 100. A method of preparing a food product rich in glucosinolates, wherein said food product is intended to be rubbed on the scalp of a patient, said method comprising germinating cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.

> 101. A method of preparing a food product rich in glucosinolates, wherein said food product is intended to be placed in a blender and subjected to homogenization, said method comprising germinating cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.

However, the composition of the "food product" is the same in all three claims. Or consider another simple example:

102. A tablet of aspirin which is useful for administering to a subject suffering from a headache.

103. A tablet of aspirin which can be placed in a plastic bottle.

What exactly, in applicants view, is the difference between the aspirin of claim 102 and that of claim 103? It is not enough to extract out a phrase from a court opinion and to assume that the phrase applies to all situations. There should also be some physical or chemical basis underpinning applicants' argument. If applicants are unable to make any such argument based on the physical realities of the situation, it renders applicants' quote from an opinion rather suspect. Nevertheless, there is another "snippet" that one could extract from *In re Cruciferous Sprout Litigation* (**64** USPQ2d 1202) In the third paragraph of the "discussion" section, the following is stated:

> "No litmus test defines when a peamble limits claim scope... ... In general a preamble limits the claimed invention if it recites essential structure..."

Thus, there is no "litmus test", and so there is no "per se" rule that the preamble is the controlling factor. Also, as stated above, "a preamble limits the claimed invention if it recites essential structure...". In the instant case, no such "essential structure" is provided by the preamble. Applicants have yet to explain what the chemical distinction might be between two liquids that are "intended to be mixed", and the same two liquids that are not

"intended to be mixed". Applicants have argued that the "two part solution of the claimed invention is [novel]". However, applicants have made no attempt to explain how a so-called "two part solution" is any different from two "one-part solutions".

Next, applicants have argued that Klein does not teach that there must be two containers in close proximity to one another. However, most of the instant claims do not impose any upper limit on the distance between the two containers. Next, applicants have made an argument about what might be emphasized by Klein. However, examiners are not limited to what may be emphasized in a given document. What matters is that which might be disclosed in the document. As disclosed at col 12, line 40+ the peptides can be "combined with any osmotically balanced aqueous solution [that is] appropriate...". In this passage, dextrose is even mentioned (col 12, line 53+). Thus, while it may be true that the emphasis of Klein is on peptides, Klein also suggests adding other osmotic agents. Furthermore, instant claims would encompass the possibility of the peptides and the glucose being present in a weight ratio of 99:1; in other words, the instant claims encompass the possiblity of emphasizing the peptides over the glucose. Thus, the claimed invention is not distinguished from the prior art on the basis of emphasis. Applicants have also asserted that since Klein suggests combinined the peptides with an "osmotically balanced aqueous solution" that somehow this teaches away from glucose. However, applicants have provided no explanation for this assertion.

Next applicants have pointed to col 5, line 24+ of Klein which provides a brief summary of one of the steps in the process of obtaining the peptide mixture. Applicants have implied that the skilled chemist would simply read col 5, lines 24-26 and nothing more. However, this would not be an accurate portrayal of what the reference teaches or what the chemist (of ordinary skill) would have gleaned from it. As it happens, the patent is replete with references to specific molecular weight ranges. One does not obtain a solution which is limited to such ranges by hydrolysis alone. The issue of obtaining the proper fraction is discussed beginning at col 8, line 46+ and continuing through col 12. This matter is further discussed in the examples, beginning at col 13, line 19+. Accordingly, the examiner reaffirms his previous statement that the peptide mixtures disclosed by Klein are quite different from whey protein hydrolyzate *per se*.

As stated on page 11, line 13-14 (instant specification), the MW distributions for the peptide mixtures are shown in figures 1-3. If one looks at figures 1-3, one sees that the peptide mixtures fall outside the scope of the Klein invention. Klein states (e.g., col 5, line 22+) that the preferred MW range is 250-750 D, which is not the case for the peptide solutions of example 1 of the instant specification. As for example 2, the protein hydrolyzate is not identified. What is stated is simply (page 13, line 25-26) "in accordance with Klein". However, this particular phrase is open to broad interpretation. First, the document is not identified, and second, no specific passage within any specific document

is identified. Thus, it could be that Elias Klein supplied a protein hydrolyzate that happened to be present in his laboratory. Or perhaps the phrase "in accordance with Klein" refers to a protein hydrolyzate prior to molecular weight fractionation. One can only speculate as to what might have been intended. Furthermore, on pages 15-16 of the instant specification, only an unidentified "whey protein hydrolyzate" is referred to. Perhaps this has relevance to the preferred solutions of USP 5039609, and perhaps not. In addition, with respect to example 2, the claims are not drawn to *a method of mitigating a dermal hypersensitivity reaction resulting from intradermal injection of a protein hydrolyzate*. The claims are drawn to the requirement for the existence of two separate vessels, one of which contains peptides, and the other of which contains glucose. Perhaps at some point in the future it will turn out that the "whey protein hydrolyzate" which was used in the hypersensitivity tests referred to in the instant specification was indeed fractionated so that the peptides were limited to the molecular weight range of 250-750 D. If evidence of this were provided at some point in the future, it would still not be effective to overcome this ground of rejection. First, it is not established that the hypersensitivity resulting from *intradermal injection* is an accurate barometer of a hypersensitivity that could potentially result from a dialysis solution being used in accordance with conventional procedures. Second, a patient might only need the dialysis for a period of a few days, in which case the hypersensitivity would not be an issue. Third,

the claims permit any ratio of glucose and to peptides to be used in the dialysis; the claims even encompass the possibility of not using glucose at all. The claims also encompass the possibility of using the glucose and the peptides consecutively, rather than simultaneously.

Thus, even if it were to turn out, at some point in the future, that a solution containing peptides and 2.5% glucose is somehow superior to a solution containing peptides and no glucose, such a showing would not be effective to overcome this rejection, given the claims in their present form. Furthermore, Klein does provide a suggestion to combine peptides with another osmotic agent, so it is not enough to merely show that there is some difference between a peptide solution containing 2.5% glucose and a peptide solution which contains no glucose. And even if, at some point in the future, it were to turn out that dialysis using 2.5% glucose + peptides produces lower hypersensitivity than a solution containing peptides and no glucose, the analysis with regard to motivation is still not complete. There are disadvantages in using glucose; this matter is discussed in Klein beginning at col 2, line 38. Thus, it is not necessarily the case that 2.5% glucose + peptides is inherently "better" than peptides alone. For some patients the combination might be better. For other patients, minimizing glucose might be better. For example, if the patient is diabetic or obese, the physician might recommend minimizing the quantity of glucose used. Perhaps such a patient would eventually develop a hypersensitivity to the Klein peptides (confined to a MW range of 250-750 D) and perhaps not. Or the physician might direct that the

dialysis be alternated between glucose and the peptide solution, a possibility which is entirely encompassed by the instant claims. Thus, for a variety of reasons, applicants' two experiments disclosed in the specification are not effective to overcome this ground of rejection.

Applicants have also argued that if the concentration of peptides is too high, uremia can develop. However, (a) applicants have not shown that patients will develop uremia if the "Klein" peptide mixtures are used, (b) if the physician overseeing the patient wants to minimize the risk of uremia, he can use a second osmotic agent as disclosed in Klein, (c) the claims do not require that glucose be used at all, and the claims permit the glucose to be used at a level far below what was used in examples 1 and 2 of the instant specification, and (d) the claims permit the glucose and peptides to be used sequentially. Therefore, if administering the peptides alone for 24 hours causes an illness, a practioner of the claimed invention would cause the illness every bit as much as a practitioner of the Klein invention. Perhaps if the claims were drawn to a method of mitigating the severity of uremia, there would be a different analysis. But the point is moot, since the claims are drawn to two separate compositions.

Applicants have also argued that in the Klein solutions, the proportion of peptides above 1200 D is sufficient to induce hypersensitivity. However, as indicated above, the solutions used in the experiments of example 2 are not relevant to the preferred peptide

mixtures of USP 5,039,609. Moreover, as stated (e.g., col 5, line 22+) the preferred MW range is 250-750 D.

Next, applicants have argued that claim 2 mandates that (a) the concentration of peptides in the claimed composition must be within the range of 1% to 8%, (b) the claimed composition must contain both glucose and peptides, and (c) the concentration of glucose in the claimed composition must be within the range of 0.5 - 8%. While part (a) and (c) might be true, part (b) is not. There is no requirement that glucose and peptides be present in the same solution. Applicants have also argued that the average molecular weight of the peptides "can be" 400-900 D. While this may be true, the point is moot. The issue pertains to the required limitations, not just to individual embodiments that might be encompassed. Applicants have also argued that not more than 25% of the peptides should have a molecular weight less than 400 D. Again, there is no such requirement. If applicants believe this is a requirement, applicants are requested to identify the exact passage in claim 2 where this is recited.

Next, applicants have attempted to dismiss Okamoto by suggesting that this reference does not disclose the use of glucose. However, this reference is replete with references to glucose. The examiner does not argue that Okamoto would form the basis for a valid §102 rejection. But taken together with the teachings of Klein, the medical specialist of ordinary skill would have arrived at the claimed invention.

The rejection is maintained.

*

Claims 2-3 are rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609), further in view of either of the following: (a) Loretti (USP 4,997,083) or (b) Larkin (USP 4,608,043).

As indicated previously, Okamoto discloses a peritoneal dialysis solution comprising glucose, and Klein teaches compositions comprising peptides for peritoneal dialysis. Loretti and Larkin both disclose sterile containers which comprise two different chambers for mixing solutions. Loretti also suggests (col 1, lines 14-24) that one compartment could house glucose, and the other amino acids.

In response, have offered little comment as to why this ground of rejection might not be justified. It appears that applicants primarily intend for the basis of their traversal to be essentially what was given in response to the §103 rejection over Okamoto in view of Klein (without the tertiary references). The examiner does the same, with one caveat. In the rejection of Okamoto in view of Klein (without the tertiary references), the question of motivation to combine a peptide solution with a glucose solution need not even be considered, since none of claims 2-5, 7, 8 actually require that the glucose solution ever be combined with the peptide solution. If the two solutions are never combined, there is no need to debate the question of whether motivation exists to combine them. Thus, a

purchasing manager of a hospital might order glucose solutions from a company in Chicago, and peptide solutions from a company in Florida. Whether the purchasing manager intends to combine the glucose with the peptides, or merely put some of the glucose in his morning coffee has no effect on the physical properties of the solutions that he has ordered.

In contrast to claims 2-5, 7, 8, claim 3 is in a somewhat different category. Although claim 3 does not actually mandate that the two solutions be combined into a single solution, the requirement that the solutions are present within a single container requires one to at least consider the possibility of combining the two solutions in some finite ratio, or using them sequentially. Thus, while the justification for rejection of claims 2, 4, 5, 7, 8 is very compelling, one can say only that the invention of claim 3 would have been obvious to a medical practioner of ordinary skill. In any case, however, the issue of motivation to combine references, and the asserted existence of "unexpected results" is discussed above.

The rejection is maintained.

*

Claims 2-5, 7, 8 are rejected under 35 U.S.C. §103 as being unpatentable over Klein USP (5,039,609) in view of Faict (USP 5092838)

The teachings of Klein were indicated previously. In addition, Klein discloses (col 3, line 64+) that peptides provide an advantage over amino acids. Faict discloses (col 5, line 15-14) a two part dialysis mixture containing glucose in one part, and histidine, or oligomers

thereof, in another.

Applicants have offered no specific commentary on this ground of rejection. It is assumed that applicants intend for the arguments presented above in the traversal of the §103 rejection over Okamoto in view of Klein to be applied here as well.

In response, the examiner does the same.

*

Claims 2-3 are rejected under 35 U.S.C. §103 as being unpatentable over Klein USP (5,039,609) in view of Faict (USP 5092838) further in view of either of the following: (a) Loretti (USP 4,997,083) or (b) Larkin (USP 4,608,043)

The teachings of Faict are indicated above; the teachings of Klein were indicated previously. As indicated above, Loretti and Larkin both disclose sterile containers which comprise two different chambers for mixing solutions. Loretti also suggests (col 1, lines 14-24) that one compartment house glucose, and the other amino acids. Neither of Loretti or Larkin disclose the specific solutions recited in instant claim 2.

It would have been obvious to combine the solutions of Faict and of Klein for additive effects, using the apparatus of Loretti or of Larkin.

*

Claims 2-5, 7, 8 are are rejected under 35 U.S.C. §103 as being unpatentable over Klein (U.S. Patent 5,039,609) in view of Steudle (U.S. Patent 5,011,826).

As indicated, Klein teaches that peptides can be used in a dialysis solution. Also disclosed (col 12, line 40+) is that the peptides can be combined with another "osmotically balanced aqueous solution...". Klein does not single out glucose for this purpose. Steudle teaches (col 4, lines 51-59) that glucose can be combined with peptides in a peritoneal dialysis solution. Applicants have argued that hindsight is required to combine the references. However, Steudle does suggest the combination of glucose and peptides (together with galactose); the medical practioner would have been motivated to select the peptide mixture disclosed by Klein to obtain the advantages asserted therein. Applicants have argued that the reference to glucose is merely "backhanded". While it may be true that Steudle does not dwell specifically on the use of glucose as an osmotic agent, the requisite disclosure is present nonetheless

The rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.